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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,727	03/29/2004	Bruno Pfeiffer	SERVIER 398 PCT	1430
7590 02/15/2007 The Firm of Hueschen and Sage 500 Columbia Plaza 350 East Michigan Avenue Kalamazoo, MI 49007			EXAMINER SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/811,727

Applicant(s)

PFEIFFER ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                               |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/11/06</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. This application claims benefit of the foreign applications: FRANCE 00.08791 with a filing date 07/06/2000; and FRANCE PCT/FR01/02169 with a filing date 07/06/2001. The certified copies of the instant foreign priority documents have been received in the Office. The foreign priority has been granted.
2. Amendment of claims 12, 15, and 17, cancellation of claims 1-11 and 19, and a declaration under 37 CFR 1.132 in the amendment filed on December 11, 2006, is acknowledged. Claims 12-18 and 20-23 are pending in the application.

### ***Information Disclosure Statement***

3. Applicant's Information Disclosure Statement, filed on December 11, 2006, has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

### ***Responses to Amendment/Arguments***

4. The rejection of claims 15 and 17 under 35 U.S.C. 112, second paragraph has been overcome in the amendment filed on December 11, 2006.
5. Since claim 19 has been cancelled, the rejection of claim 19 under 35 U.S.C. 112, first paragraph has been obviated herein.
6. Applicant's arguments regarding the rejection of claims 12-18 and 20-23 under 35 U.S.C. 102(b) over Vincent et al. US 4,914,214, filed on December 11, 2006, have been fully considered and they are persuasive. Applicant's declaration indicates that the instant X-ray pattern data is distinct from Vincent et al.

see pages 2/5-3/5 of declaration. Applicants also indicate that the gamma crystalline form of the instant compound is stable in 37 days, while Vincent et al. crystalline form is not stable after one month under the same conditions. Therefore, Vincent et al. crystalline form does not anticipate the instant gamma crystalline of the instant compound/composition and its processes of making and method of use, the rejection of claims 12-18 and 20 -23 under 35 U.S.C. 102(b) has been withdrawn. Since claim 19 has been cancelled, the rejection of claim 19 under 35 U.S.C. 102(b) has been obviated herein.

7. Applicant's arguments regarding the rejection of claims 20 and 22-23 under 35 U.S.C. 102(a) or 102(e) over Guez et al. US 6,653,336 filed on December 11, 2006, have been fully considered and they are not persuasive. Since Guez et al. (i.e., same assignee) disclose the same compound and its pharmaceutical composition comprising a diuretic indapamide, the rejection of claims 20 and 22-23 under 35 U.S.C. 102(a) or 102(e) is maintained. A side-by-side comparison disclosing distinctness between Guez et al. and the instant claims would obviate the rejection.

8. Applicant's arguments regarding the rejection of claims 12-18 and 20-23 under 35 U.S.C. 103(a) over Vincent et al. '214 in view of Guez et al. US '336 or Brittan's publication filed on December 11, 2006, have been fully considered and they are not persuasive. Guez et al. (i.e., same assignee) disclose the same compound and its solid pharmaceutical composition comprising a diuretic indapamide. Vincent et al.

Art Unit: 1626

disclose the same crystalline compound with an unstable status compared with the instant gamma form of the same compound. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, Vincent et al. unstable crystal form and the instant form  $\gamma$ , after mixing, grinding, compressing would both be transformed into the same thermodynamically stable form(s) of the instant claimed  $\gamma$  form, see Brittain's publication, pages 348-361. Vincent et al. or Guez et al. compound perindopril of tert-butylamine salt is used for treating arteriolo-capillary microcirculatory disorders(i.e., cardiovascular diseases), see columns 1-4. Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed crystalline forms and its compositions of known compounds would have been suggested to one skilled in the art. The rejection of 12-18 and 20-23 under 35 U.S.C. 103(a) over Vincent et al. '214 in view of Guez et al. US '336 or Brittan's publication, is maintained. Since claim 19 has been cancelled, the rejection of claim 19 under 35 U.S.C. 103(a) has been obviated herein.

9. Applicant's arguments regarding the rejection of claims 12-18 and 20-23 under the obviousness-type double patenting over 1, 8-9, and 11-12 of Pfeiffer et al. co-pending application No. 11/052,489, or over claims 14, 22-23, and 25-26 of Pfeiffer et al. co-pending application No. 10/792,355 in view of Brittain's publication, have been fully considered and they are persuasive, in part. Since the X-ray diffraction data of the instant gamma form crystalline and its processes of making are distinct from the beta

Art Unit: 1626

form of Pfeiffer et al. '489 or alpha form of Pfeiffer et al. '355, the rejection of claims 12-18 under the obviousness-type double patenting has been withdrawn herein. However, it is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, Pfeiffer et al. alpha or beta crystal form and the instant form gamma form, after mixing, grinding, compressing would both be transformed into the same thermodynamically stable form(s) of the instant claimed  $\gamma$  form, see Brittain's publication, pages 348-361. Pfeiffer et al. compound perindopril of tert-butylamine salt and its compositions is used for treating arteriolo-capillary microcirculatory disorders(i.e., cardiovascular diseases). Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed pharmaceutical compositions of known compounds/compositions would have been suggested to one skilled in the art. The rejection of claims 20-23 under the obviousness-type double patenting, is maintained. Since claim 19 has been cancelled, the rejection of claim 19 under the obviousness-type double patenting has been obviated herein. Applicants are requested to file terminal disclaimers to overcome the rejection.

**10. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1626

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

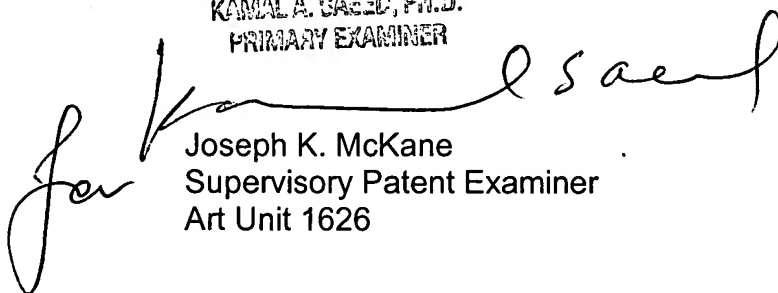
Application/Control Number: 10/811,727

Page 7

Art Unit: 1626

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAMAL A. SAED, Ph.D.  
PRIMARY EXAMINER

A large, stylized handwritten signature in black ink, appearing to read 'Joe K. McKane', is written over the printed name and title of Joseph K. McKane.

Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626

A small, handwritten signature in black ink, appearing to read 'R. Shiao', is written over the printed name and title of Robert Shiao.

Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

February 12, 2007